

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ )  
FENFLURAMINE/DEXFENFLURAMINE) ) MDL NO. 1203  
PRODUCTS LIABILITY LITIGATION )  
 )  
THIS DOCUMENT RELATES TO: )  
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SHEILA BROWN, et al. ) CIVIL ACTION NO. 99-20593  
 )  
 v. )  
 )  
AMERICAN HOME PRODUCTS ) 2:16 MD 1203  
CORPORATION )  
 )  
 )  
THIS DOCUMENT RELATES TO: )  
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LINDA MILO )  
 )  
 v. )  
 )  
PFIZER, et al. )  
 )

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9037

Bartle, J.

April 1, 2013

Plaintiff Linda Milo has filed a lawsuit in the Court of Common Pleas of Philadelphia County against defendants Pfizer, Inc., Wyeth Pharmaceuticals Inc., Wyeth-Ayerst International Inc., and Wyeth LLC (collectively "Wyeth").<sup>1</sup> See Milo v. Pfizer, et al., C.P. Phila., May Term, 2011, Case No. 00047. Ms. Milo alleges that she suffers from primary pulmonary hypertension

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1. Pfizer became the parent company of Wyeth in October 2009. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

("PPH") as a result of ingesting Wyeth's diet drugs known as Pondimin (fenfluramine) and Phentermine.

Pending before the court is Wyeth's motion to enjoin plaintiff from proceeding with her state court action pursuant to Pretrial Order No. 2383 on the ground that she is a class member in Brown v. American Home Products Corp., MDL No. 1203, and is barred by the Settlement Agreement approved by this court from litigating her pending claim.

This court approved the Settlement Agreement of this massive and complex diet drug class action in PTO No. 1415, In re Diet Drugs, No. 99-20593, 2000 WL 1222042 (E.D. Pa. Aug. 28, 2000). With certain exceptions, Ms. Milo, as a class member, released all claims she had or may have against Wyeth for her use of diet drugs. The exception which is the focus of the pending motion allows class members to sue Wyeth in the tort system if they suffer from PPH, a fatal disease which can be caused by the use of Wyeth's diet drugs.

This court set forth in PTO No. 2383 the procedures for determining whether a class member who claims a PPH diagnosis qualifies as a threshold matter for the legal definition of that condition, and whether he or she is permitted to maintain a lawsuit against Wyeth alleging PPH. PTO No. 2383 states that a putative PPH plaintiff must demonstrate full compliance with all three parts of the definition of PPH as set forth in the settlement agreement in order to be able to maintain his or her lawsuit.

As explained in PTO No. 2623, "This court has the job of overseeing the settlement of this massive class action, particularly to insure that the Settlement Agreement, as approved by the court, is uniformly interpreted and properly enforced." Pursuant to that role, this court must first make a determination as to whether there exists at least a genuine dispute of material fact that plaintiff suffers from PPH as defined in the Settlement Agreement. If plaintiff has not come forward with evidence to create such a genuine dispute, the court will enjoin her from proceeding with her lawsuit. If, on the other hand, plaintiff presents such evidence, the case may proceed to trial where it will be determined whether Wyeth is liable. See PTO No. 1415; PTO No. 3699.

The definition of PPH in the Settlement Agreement requires, among other factors, the following objective evidence from medical records:

Mean pulmonary artery pressure by cardiac catheterization of  $\geq 25$  mmHg at rest or  $\geq 30$  mmHg with exercise with a normal pulmonary artery wedge pressure  $\leq 15$  mmHg...

Settlement Agreement § I.46a(1)(a). Plaintiff submitted the results of nine diagnostic tests in support of her PPH claim. The cardiac catheterization of September 3, 2007 shows a pulmonary artery pressure of 47/13 with no mean reported, and a pulmonary artery wedge pressure of 25 mmHg. The cardiac catheterization of October 29, 2007 shows a mean pulmonary artery pressure of 27 mmHg but a mean pulmonary artery wedge pressure of

22 mmHg. The cardiac catheterization of November 2, 2011 shows a mean pulmonary artery pressure of 22 mmHg with a mean pulmonary capillary wedge pressure of 9 mmHg.<sup>2</sup>

Wyeth argues that plaintiff has failed to meet the required definition of PPH because none of her cardiac catheterization tests shows both a mean pulmonary artery pressure of greater than or equal to 25 mmHg and a pulmonary artery wedge pressure of less than or equal to 15 mmHg.

Plaintiff's response is two-fold. First, she asserts that her October 29, 2007 catheterization meets the definition of PPH because Dr. Michael Mollod, the physician who performed the diagnostic test, reported a left ventricular end-diastolic pressure ("LVEDP") of 15 mmHg. Second, plaintiff argues that Wyeth's motion to enjoin her action is untimely.

In urging the court to accept the LVEDP measurement in lieu of a pulmonary artery wedge pressure measurement, plaintiff relies on the expert report of Dr. Lewis Rubin. Dr. Rubin's book Primary Pulmonary Hypertension (1997) is the authority cited for the definition of PPH in Section I.46 of the Settlement Agreement. In his report, Dr. Rubin states that a LVEDP

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2. Plaintiff asserts that Wyeth misstated the results of her October 29, 2007 catheterization. While plaintiff is correct that the Report created by Dr. Mollod following the procedure indicates a pulmonary capillary wedge artery pressure of 38/11 with no reported mean, the raw data plainly shows that the pulmonary artery wedge pressure was 27/25 with a mean of 22, as stated by Wyeth. In any event, plaintiff does not argue that her pulmonary artery wedge pressure was less than or equal to 15 mmHg.

measurement satisfies Section I.46a(1)(a) of the Settlement Agreement. He bases this conclusion on the fact that while a pulmonary artery wedge pressure measurement is a mere estimate of the filling pressure, the LVEDP measurement is the definitive measurement of filling pressure.

The Settlement Agreement, which binds the parties, must be interpreted "according to basic contract principles, and when its terms are clear and unambiguous, its meaning must be determined from the four corners of the contract." In re Diet Drugs ("Cauthen"), \_\_ F.3d \_\_, 2013 WL 210195 (3d Cir. Jan. 28, 2013). Regardless of whether LVEDP may be a more accurate measurement of filling pressure for the purposes of diagnosing PPH, plaintiff cannot satisfy Section I.46a(1)(a) of the Settlement Agreement on the basis of a LVEDP measurement. She is required by its plain terms to present a pulmonary artery wedge pressure measurement of less than or equal to 15 mmHg. The fact that Dr. Rubin believes LVEDP to be an equal or superior measurement of filling pressure for the purposes of a PPH diagnosis is irrelevant. See Cauthen, 2013 WL 210195, at \*4.

Plaintiff does not challenge Wyeth's assertion that she must satisfy both components of Part I.46a(1)(a) of the Settlement Agreement with measurements from a single catheterization. We agree with Wyeth that plaintiff cannot "mix and match" results from different procedures. See PTO No. 2793 (Wyeth v. Ashby, Mar. 14, 2003). While plaintiff's pulmonary artery pressure measured on October 29, 2007 and her pulmonary

artery wedge pressure of November 2, 2011 both fall in the accepted range for a PPH diagnosis, they were performed on different days. In sum, plaintiff has failed as a threshold matter to meet the requirements of § I.46a(1)(a) of the Settlement Agreement. See PTO No. 2383.

Plaintiff also argues that Wyeth's pending motion filed on February 18, 2013 is untimely. We disagree. PTO No. 2383 requires only that Wyeth use its "best efforts" to file and serve a motion to enforce Paragraph 7 of PTO No. 1415 within sixty days of receipt of medical evidence.<sup>3</sup> While Wyeth waited eighteen months after the initial receipt of medical documents to file its motion to enjoin plaintiff from proceeding with her state court lawsuit, there is no evidence that Wyeth did not use its best efforts to comply with PTO No. 2383. Wyeth continued to receive plaintiff's medical files into the fall of 2012 and prompted plaintiff several times for her position on how she intended to satisfy PTO No. 2383.

Accordingly, the motion of Wyeth to enjoin plaintiff from proceeding with her state court action will be granted.

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3. Paragraph 7 of PTO No. 1415 provides: "The court hereby bars and enjoins all class members who have not, or do not, timely and properly exercise an Initial, Intermediate, Back-End or Financial Insecurity Opt-Out right from asserting, and/or continuing to prosecute against AHP or any other Released Party any and all Settled Claims which the class member had, has or may have in the future in any federal, state or territorial court."